

PATENT
Customer No. 22,852
Attorney Docket No. 4121.0003-02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
SORGE et al.) Group Art Unit: 1637
Application No.: 08/529,767) Examiner: J. Fredman
Filed: September 15, 1995)
For: NOVEL POLYMERASE)
COMPOSITIONS AND USES)
THEREOF)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

ATTN: Michael Woodward
Crystal Mall 1 - 7th Floor

Sir:

INFORMATION DISCLOSURE STATEMENT

05/29/2003 MPEOPLE 00000002 08529767
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Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), Applicants bring to the attention of the

Examiner the documents listed on the attached form and the following information. This

Information Disclosure Statement is being filed after the events recited in

Section 1.97(b). To the undersigned's knowledge, there is no current Final Office

Action, Notice of Allowance, or action that otherwise closes prosecution.¹ Under the

¹ A Final Office Action was mailed February 24, 1997. The Supplemental Amendment that was filed December 10, 1997, confirms a telephone discussion in which Examiner Campbell stated that the finality of that Office Action was being withdrawn and that the application was in condition for allowance. Subsequent to December 10, 1997, no written communications in this case have been received from the United States Patent and Trademark Office ("USPTO"). The Third Supplemental Amendment that was filed January 28, 2003, reports a telephone call with Examiner Fredman, in which Examiner Fredman noted that claim 9 had depended from a canceled claim. In the Third Supplemental Amendment, claim 9 was canceled without prejudice or disclaimer.

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provisions of 37 C.F.R. § 1.97(c), this Information Disclosure Statement is accompanied by a fee of \$180.00 as specified by Section 1.17(p).

Copies of the listed documents are attached. One of those documents is a copy of the Request for Reexamination for parent U.S. Patent No. 5,556,772 ("the '772 patent"). One of those documents is a copy of the Notice of Reexamination Request Filing Date, which was mailed from the USPTO. Several of those documents are copies of documents from the following three U.S. District Court litigations involving the '772 patent:

Stratagene v. Invitrogen Corporation ("Invitrogen"), United States District Court for the District of Maryland, Southern Division, Civil Action No. DKC 01-3566 ("Case 1");

Stratagene v. Takara Holdings, Inc. and Takara Bio, Inc. ("Takara"), United States District Court for the District of Maryland, Southern Division, Civil Action No. WMN 02 CV 3603 ("Case 2"); and

Takara Bio, Inc. v. Stratagene, United States District Court for the Southern District of California, Case No. 03 CV 0742B AJB ("Case 3").²

In Case 1, Stratagene asserted that Invitrogen infringed the '772 patent. In Case 1, Invitrogen has alleged that the '772 patent is unenforceable in view of alleged inequitable conduct and is invalid under 35 U.S.C. § § 102 and 103. Information related to Invitrogen's allegations of inequitable conduct and invalidity are contained, e.g., in the enclosed copies of: (1) Invitrogen Corporation's Answer to Complaint For Patent Infringement And Counterclaim and (2) Expert Opinion of Thomas G. Wiseman, Esq.

² Applicants also enclose copies of docket sheets for each of those three cases, which provide a list of pleadings filed in those cases. If the USPTO requests copies of further documents, they will be provided to the extent permissible under the protective order.

("Wiseman Opinion"). Invitrogen also submitted an Expert Report of Thomas A. Kunkel, Ph.D. ("Kunkel Report"), which also discusses certain positions on certain issues such as invalidity, claim construction, and infringement. The undersigned was informed by Stratagene's litigation counsel Marc Labgold that the Kunkel Report cannot be submitted to the USPTO in view of the protective order in the litigation by which Invitrogen has designated certain information as confidential.

The assertions of invalidity by Invitrogen, including those in the Wiseman Opinion and the Kunkel Report, are summarized as follows. Invitrogen alleges that U.S. Patent 5,436,149 to Barnes anticipates claims 1 to 13 of the '772 patent. Invitrogen also alleges that claims 1 to 13 of the '772 patent are obvious to what they have defined as one of ordinary skill in the art over either Perrino and Loeb, *Proc. Natl. Acad. Sci., USA*, 86(9):3085-3085 (1989) or Perrino and Loeb, *Biochemistry*, 29(22):5226-5231 (1990) alone, or in combination with Tindall and Kunkel, *Biochemistry*, 29:16):6008-6013 (1988) ("Tindall and Kunkel") and Lundberg, *Gene*, 108:1-6 (1991) or with Tindall and Kunkel and the New England Biolab catalog on Deep Vent® DNA polymerase (1992).

Information related to Stratagene's positions on Invitrogen's allegations of inequitable conduct and invalidity are contained, e.g., in the enclosed copies of: (1) Stratagene's Answer to Invitrogen Corporation's Counter Claim and (2) Expert Witness Report of John F. Witherspoon.

Stratagene also submitted an Expert Statement of Joseph O. Falkinham, III and Rebuttal Report of Joseph O. Falkinham, III, Ph.D., which also discusses certain positions on certain issues such as invalidity, claim construction, and infringement. The undersigned was informed by Stratagene's litigation counsel Marc Labgold that copies

of those two papers cannot be submitted to the USPTO in view of the protective order in the litigation by which Invitrogen has designated certain information as confidential.

In Case 2, Stratagene asserted that Takara infringed the '772 patent. Takara's "Motion to (1) Quash Service of Process, (2) Dismiss for Inadequate Service of Process, and (3) Dismiss for Lack of Personal Jurisdiction, or (4) -- If This Court Has Jurisdiction - - Transfer" ("Takara Motion"), Takara alleges work of Wayne Barnes prior to the February 19, 1993, filing date of the application that issued into U.S. Patent No. 5,436,149 (Takara Motion at 2). The Takara Motion also discusses alleged activity of Barnes relative to Stratagene (*Id.* at 2 and 3). The Takara Motion also mentions an alleged dispute regarding issues relating to inventorship of the '772 patent (*Id.* at 3).

In Case 3, Takara Bio requests correction of inventorship of the '772 patent to include Wayne Barnes as an inventor. Takara Bio's Complaint Under the Patent Law ("Takara Bio Complaint") includes allegations related to Takara Bio's request to correct inventorship of the '772 patent.

Applicants respectfully request that the Examiner consider the listed documents and information discussed in this Information Disclosure Statement and evidence that consideration by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law,

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Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the claimed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: May 27, 2003

By: Charles E. Van Horn #40266
for M. Paul Barker
Reg. No. 32,013

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INFORMATION DISCLOSURE CITATION

Atty. Docket No.	4121.0003-02000	Appln. No.	08/529,767
Applicant	SORGE et al.	Examiner:	Fredman, J.
Filing Date	September 15, 1995	Group:	1637

less U.S. PATENT DOCUMENTS

Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
	5,436,149	July 25, 1995	Barnes			
	5,556,772	Sept. 17, 1996	Sorge et al.			

FOREIGN PATENT DOCUMENTS

Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
WO 92/09689	June 11, 1992	PCT			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Barnes, W. "The fidelity of <i>Taq</i> polymerase catalyzing PCR is improved by an N-terminal deletion," <i>Gene</i> , 112: 29-35 (1992).
	Lundberg et al. "High-fidelity amplification using a thermostable DNA polymerase isolated from <i>Pyrococcus furiosus</i> ," <i>Gene</i> , 108: 1-6 (1991).
	Ohler et al. "Optimization of Long-distance PCR using a transposon-based model system," <i>PCR Methods and Applications</i> , 2: 51-59 (1992).
	Perrino et al., "Hydrolysis of 3'-terminal mispairs in vitro by the 3' → 5' exonuclease of DNA polymerase δ permits subsequent extension by DNA polymerase α ," <i>Biochemistry</i> , 29: 5226-5231 (1990).
	Perrino et al., "Proofreading by the ϵ subunit of <i>Escherichia coli</i> DNA polymerase III increases the fidelity of calf thymus DNA polymerase α ," <i>Proc. Natl. Acad. Sci. USA</i> , 86: 3085-3088 (1989).
	Tindall et al., "Fidelity of DNA synthesis by the <i>Thermus aquaticus</i> DNA polymerase," <i>Biochemistry</i> , 27: 6008-6013 (1988).
	New England BioLabs catalog on Deep Vent DNA _R TM Polymerase, page 61 (1992).
	New England Biolabs catalog on Deep Vent _R ® polymerase, page 62, submitted in Exhibit E of the Request for Reexamination Under 37 C.F.R. §1.510 (for U.S. Patent No. 5,556,772) filed by Kate Murashige on March 20, 2003, and alleged to be dated 1992 in that Request for Reexamination.
	The American Heritage College Dictionary, Third Edition, Houghton Mifflin Company, page 750, submitted in Exhibit H of the Request for Reexamination Under 37 C.F.R. §1.510 (for U.S. Patent No. 5,556,772) filed by Kate Murashige on March 20, 2003.
	http://bio.takara.co.jp/BIO_EN/Catalog_d.asp?C_ID=C0173 (12/19/2002) (6 pages), submitted in Exhibit J of the Request for Reexamination Under 37 C.F.R. §1.510 (for U.S. Patent No. 5,556,772) filed by Kate Murashige on March 20, 2003
	http://bio.takara.co.jp/BIO_EN/Catalog_d.asp?C_ID=C0174 (12/19/2002) (5 pages), submitted in Exhibit J of the Request for Reexamination Under 37 C.F.R. §1.510 (for U.S. Patent No. 5,556,772) filed by Kate Murashige on March 20, 2003

INFORMATION DISCLOSURE CITATION

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Applicant	SORGE et al.	Examiner:	Fredman, J.
Filing Date	September 15, 1995	Group:	1637

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	http://www.Stratagene.com/displayProduct.asp?productId=104 (12/19/2002) (2 pages), submitted in Exhibit K of the Request for Reexamination Under 37 C.F.R. §1.510 (for U.S. Patent No. 5,556,772) filed by Kate Murashige on March 20, 2003
	Stratagene product information, TaqPlus® Long and TaqPlus® Precision PCR Systems (2 pages), submitted in Exhibit K of the Request for Reexamination Under 37 C.F.R. §1.510 (for U.S. Patent No. 5,556,772) filed by Kate Murashige on March 20, 2003
	Declaration of Joseph A. Sorge and Rebecca L. Mullinax Under 37 C.F.R. §1.131 from U.S. Application No. 08/197,791, submitted in Exhibit G of the Request for Reexamination Under 37 C.F.R. §1.510 (for U.S. Patent No. 5,556,772) filed by Kate Murashige on March 20, 2003

OTHER DOCUMENTS (from Stratagene v. Invitrogen Corp.)

	U.S. District Court, District of Maryland (Greenbelt), Civil Docket for Case #: 8:01-cv-03566-DKC
	Civil Cover Sheet
	Complaint for Patent Infringement
	Invitrogen Corporation's Answer to Complaint for Patent Infringement and Counterclaim
	Stratagene's Answer to Invitrogen Corporation's Counter Claim
	Expert Opinion of Thomas G. Wiseman, Esq.
	Expert Witness Report of John F. Witherspoon

OTHER DOCUMENTS (Stratagene v. Takara Holdings, Inc., et al.)

	U.S. District Court, District of Maryland (Baltimore), Civil Docket for Case #: 1:02-cv-03603-WMN
	Civil Cover Sheet
	Complaint for Patent Infringement
	Takara's Motion to (1) Quash Service of Process, (2) Dismiss For Inadequate Service of Process, and (3) Dismiss for Lack of Personal Jurisdiction, or (4) -- If This Court Has Jurisdiction -- Transfer

OTHER DOCUMENTS (Takara Bio Inc. v. Stratagene, et al.)

	U.S. District Court, Southern District of California (San Diego) Civil Docket for Case #: 03-CV-742
	Civil Cover Sheet
	Complaint Under the Patent Law
	Notice of Related Case
	Notice of Party with Financial Interest [Local Rule 40.2]

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Atty. Docket No.	4121.0003-02000	Appln. No.	08/529,767
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OTHER DOCUMENTS (Takara Bio Inc. v. Stratagene, et al.)

	Stipulation Extending Time to File a Responsive Pleading; Order
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OTHER DOCUMENTS (Related to Request for Reexamination)

	Request for Reexamination Under 37 C.F.R. §1.510 (for U.S. Patent No. 5,556,772) filed by Kate Murashige on March 20, 2003
	Exhibits A-K
	Transmittal Form
	Post card
	Fee Transmittal

Examiner	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	
Form PTO 1449	Patent and Trademark Office - U.S. Department of Commerce